

Application No. 10/669,313
Amendment "B" dated March 22, 2006
Reply to Office Action mailed February 28, 2006

AMENDMENTS TO THE SPECIFICATION

Please insert the following paragraphs on page 12, line 3:

FIGS. 19A-19C are, respectively, views of a bioabsorbable clip and fastener of the present invention shown in top view in a delivery configuration, in side view in the delivery configuration, and in side view in a deployed configuration.

FIGS. 20A and 20B are isometric views of an alternative embodiment of the bioabsorbable surgical clip and fastener, constructed in accordance with the present invention and shown, respectively, in a delivery configuration and in a deployed configuration.

FIGS. 21A-21B through 24A-24B are side-sectional views of the closure component in use at a vascular puncture site.

Please insert the following paragraphs on page 33, after line 5:

With reference now to FIGS. 19A-19C, bioabsorbable clip 846 and fastener 860 are described in greater detail. FIG. 19A shows clip 846 in the delivery configuration. Clip 846 comprises curved legs 870 and proximal end 872. Legs 870 distally terminate at spikes 874 with optional engagement means 876, and proximally terminate at narrowed region 878. Engagement means 876 may comprise, for example, barbs or hooks.

Fastener 860 comprises bioabsorbable locking collar 880, which is slidably received on the exterior of clip 846. As seen in FIG. 19B, locking collar 880 may be distally advanced down the exterior of clip 846 to deform the clip to its deployed configuration, wherein curved legs 870 and spikes 874 are drawn together. Clip 846 may then be separated from clip holder 856 by rotating proximal end 872 with respect to legs 870, causing the clip to snap into two pieces at

Application No. 10/669,313
Amendment "B" dated March 22, 2006
Reply to Office Action mailed February 28, 2006

narrowed region 878, for the reasons described hereinafter. Clip 846 and locking collar 880 preferably are fabricated from bioabsorbable materials, such as polyglycolic acid.

Referring to FIG. 20, an alternative embodiment of the closure component of the present invention is described. Closure component 890 comprises bioabsorbable clip 892 and fastener 894. Clip 892 comprises proximal hoop 896 with narrowed regions 898, and legs 900 terminating in spikes 902. Fastener 894 comprises bioabsorbable wedge 904. Wedge 904 has a diameter substantially equal to the diameter of hoop 896 at its distal end, the diameter tapering to a maximum diameter at the proximal end of wedge 904. Clip 892 therefore may be deformed from the delivery configuration of FIG. 20A to the deployed configuration of FIG. 20B, wherein legs 900 and spikes 902 are drawn together, by advancing wedge 904 into hoop 896 to deform clip 892 at narrowed regions 898. Lumen 906 extends through hoop 898 of clip 892, while lumen 908 extends through wedge 896. Clip 892 and wedge 896 therefore are configured for delivery over the exterior of an introducer sheath. The clip and wedge preferably are fabricated from bioabsorbable materials.

With reference to FIGS. 21A-21B through 24A-24B, in conjunction with FIGS. 1-3, methods of using vascular device 10 are described. Introducer sheath 12 is advanced through skin, fat, and muscle tissue into vessel V, through vascular puncture P, which is formed in accordance with well-known techniques. Vascular device 10 is used in the same manner as a standard introducer sheath.

As shown in FIG. 21A, distal pins 850, mounted in housing 816, abut distal slots 866 and 868 of drivers 858 and holders 856, respectively.

FIG. 21B illustrates closure component 820 via sectional views. FIG. 21A shows the locations of proximal pins 854 within proximal slots 862 and 864, and the locations of distal pins

Application No. 10/669,313
Amendment "B" dated March 22, 2006
Reply to Office Action mailed February 28, 2006

850 within distal slots 866 and 868, corresponding to the relative longitudinal positions of clip holders 856 and locking collar drivers 858 depicted in FIG. 21B. Pin locations are shown via side views of clip holders 856 and locking collar drivers 858 at the relevant locations.

As seen in FIGS. 21A and 21B, with clip housing 816 positioned at puncture site P, proximal pins 854, mounted in caps 852, are positioned at the extreme right of proximal driver slots 862 and of the circumferential portions of proximal holder slots 864. Distal pins 850 are located at the distal end of distal driver slots 866 and of the longitudinal portions of distal holder slots 868.

In FIGS. 22A and 22B, with clip housing 816 held immobile, force is applied to caps 852 to distally advance clips 846 with respect to housing 816. Specifically, proximal pins 854 abut and apply force against proximal slots 862 and 864, which advances drivers 858 and clip holders 856, as well as attached clips 846 and locking collars 880. Distal pins 850 move freely within distal slots 866 and the longitudinal portions of distal slots 868. Distal advancement of clips 846 continues until pins 850 abut against the proximal end of the longitudinal portions of distal holder slots 868 of clip holders 856. Drivers 858 likewise are restrained by their connection to clip holders 856 via proximal pins 854. The tissue-engaging members, spikes 874 and engagement means 876, of clips 846 contact and pierce the wall of vessel V on opposite sides of the puncture site P.

As seen in FIGS. 23A and 23B, once the spikes have pierced the vessel wall, locking collar drivers 858 are advanced distally while clip housing 816 and clip holders 856 remain stationary, thereby distally advancing locking collars 880 down the exteriors of clips 846 to draw legs 870 and spikes 874 together to close puncture P. Engagement means 876 serve to retain the clips within the vessel wall during healing.

Application No. 10/669,313
Amendment "B" dated March 22, 2006
Reply to Office Action mailed February 28, 2006

To achieve this advancement of drivers 858 with respect to clip holders 856, caps 852 are rotated clockwise, as viewed from above, until proximal pins 854 abut against the extreme left of proximal slots 862 and 864, thereby aligning the pins with the longitudinal portions of proximal holder slots 864. Then, force is once again applied to caps 852 to advance drivers 858 and deform clips 846 to their deployed configurations. Specifically, proximal pins 854 abut and apply force to proximal driver slots 862, thereby distally advancing drivers 858. Pins 854 move freely within the longitudinal portions of proximal holder slots 864 until they abut against the distal ends of slots 864. Likewise, distal driver slots 866 move freely until distal pins 850 abut the proximal ends of slots 866. In FIG. 23A, when proximal pins 854 abut slots 864 and distal pins 850 abut slots 866, locking collars 880 have been driven down the exteriors of clips 846, thereby deforming the clips to draw legs 870 together and close the puncture site.

In FIGS. 24A and 24B, with clips 846 deformed to seal puncture P, clip holders 856 are detached from clips 846 by snapping the clips free at narrowed regions 878. At this point, or prior to detachment, a suitable biocompatible bioglue or tissue sealant optionally may be injected into the puncture tract, as discussed hereinabove, through device port 832 or side port 822, to aid in sealing vascular puncture P. Alternatively, the bioglue or tissue sealant may be delivered through the backbleed path described above. Vascular device 10 then is withdrawn from the vessel wall, completing the procedure.

Clips 846 are detached from clip holders 856 by rotating caps 852 counterclockwise, as viewed from above. Proximal pins 854 of caps 852 move freely within proximal driver slots 862, but abut against the distal end of the longitudinal portions of proximal holder slots 864 and cause clip holders 856 to rotate with respect to collar drivers 858. Distal pins 850 of clip housing 816 move freely within the circumferential portions of distal holder slots 868 during rotation of clip

Application No. 10/669,313
Amendment "B" dated March 22, 2006
Reply to Office Action mailed February 28, 2006

holders 856. Meanwhile, drivers 858 are restrained from rotation by distal pins 850, which abut against distal driver slots 866. Bioabsorbable clips 846 do not rotate because the square cross section of square clip bores 847 of drivers 858 matches the substantially square cross section of clips 846, thus, since drivers 858 are restrained from rotation, so are clips 846. Non-square cross sections for clips 846 and bores 847, capable of performing the restraining function, will be apparent to those of skill in the art and fall within the scope of the present invention.

Since clips 846 are restrained while clip holders 856 rotate, and since proximal ends 872 of clips 846 are attached to clip holders 856, counterclockwise rotation of caps 852 causes clips 846 to snap at their weakest points: narrowed regions 878. Vascular device 10 may then be removed from the patient to complete the procedure.

Although preferred illustrative embodiments of the present invention are described above, it will be evident to one skilled in the art that various changes and modifications may be made without departing from the invention. For example, with minor modifications, vascular device 10 may be configured to carry closure component 890 of FIG. 20, or any of a variety of alternative bioabsorbable and deformable clips. Proximal pins 854 may be formed integrally with caps 852, and distal pins 850 may be formed integrally with clip housing 816. Any number of clips 846 may be used to close the vascular puncture.